EXHIBIT B

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November 7, 2011

The Honorable F. Dennis Saylor, IV
United States District Judge
United States District Court
Donohue Federal Building
595 Main Street
Worcester, MA 01608

Re: *Abbott GmbH & Co., KG et al. v. Centocor Ortho Biotech, Inc., et al.*, C.A. No. 4:09-cv-11340; *Centocor Ortho Biotech, Inc. v. Abbott GmbH & Co., KG*, C.A. No. 1:09-cv-01653

Dear Judge Saylor:

This letter is submitted on behalf of Abbott in order to advise the Court of *Streck, Inc. v. Research & Diagnostic Sys., Inc.*, No. 2011-1045 (Fed. Cir. Oct. 20, 2011), a recent decision from the U.S. Court of Appeals for the Federal Circuit pertaining to 35 U.S.C. § 146 actions, a copy of which is enclosed.

As the Court is aware, the referenced cases involve (1) Abbott's claims of patent infringement against Centocor (4:09-cv-11340), and (2) Centocor's Section 146 action against Abbott challenging the outcome of the interference concerning claims of Abbott's '128 patent and a Centocor patent application (1:09-cv-01653). In the infringement action, Abbott has moved for summary judgment that Centocor is collaterally estopped from relitigating issues relating to validity that were or could have been raised in the interference. *See* Abbott's Motion for Summary Judgment No. 2.

The Section 146 issues addressed in *Streck* are not relevant to the collateral estoppel issue presented in Abbott's motion. However, they do relate to certain contentions in Centocor's opposition to that motion regarding the proper standard of review in Section 146 actions. *See* Centocor's Opposition Brief at 18-19.

In *Streck* the infringement action had been tried first and the issue concerned the use of the record from the infringement proceeding in the Section 146 action. With respect to the standard of review in a Section 146 proceeding, the *Streck* court stated that "the district court appropriately considered additional evidence and conducted a *de novo* determination of the issue of priority under § 146" based on that additional evidence. *See Streck, Inc.*, No. 2011-1045, slip op. at 8-9.

While the *Streck* decision addresses the standard of review in Section 146 Actions, that issue is irrelevant to Abbott's motion, which addresses the collateral estoppel effect of the interference proceedings on the separate infringement action. *See* Abbott's Reply Memorandum

in Support Its Motion for Summary Judgment No. 2 at 10. Nor does *Streck* address the issue of whether a party may raise new issues or arguments in a Section 146 proceeding. *See Conservolite, Inc. v. Widmayer*, 21 F.3d 1098, 1102 (Fed. Cir. 1994) (explaining limits on offering new evidence in Section 146 actions). We bring this decision to the Court's attention solely in the interest of completeness given certain of the arguments raised by Centocor.

Respectfully yours,

William F. Lee /mw

William F. Lee

Enclosure

cc: Dianne B. Elderkin (via email)
Barbara L. Mullin (via email)

United States Court of Appeals for the Federal Circuit

STRECK, INC.,
Plaintiff-Appellee,

v.

RESEARCH & DIAGNOSTIC SYSTEMS, INC.,
Defendant-Appellant.

2011-1045

Appeal from the United States District Court for the District of Nebraska in Case No. 09-CV-0410, Chief Judge Joseph F. Bataillon.

Decided: October 20, 2011

Floyd R. Nation, Winston & Strawn LLP, of Houston, Texas, argued for plaintiff-appellee. With him on the brief were Merritt D. Westcott and Melinda K. Lackey. Of counsel on the brief was Richard L. Stanley, of Houston, Texas.

Martin M. Zoltick, Rothwell, Figg, Ernst & Manbeck, P.C., of Washington, DC, argued for defendant-appellant. With him on the brief were Kurt J. Niederluecke and Grant D. Fairbairn, of Fredrikson & Byron, of Minneapolis, Min-

nesota. Of counsel was Glenn E. Karta, Rothwell, Figg, Ernst & Manbeck, of Washington, DC.

Before NEWMAN, O'MALLEY, and REYNA, *Circuit Judges*.

NEWMAN, *Circuit Judge*.

This appeal is from the judgment of the United States District Court for the District of Nebraska, deciding the question of priority of invention in an action brought under 35 U.S.C. §146 ("Civil action in case of interference"). The district court awarded priority to the senior party, Streck, Inc.[1] The junior party, Research & Diagnostic Systems, Inc. ("R&D"), appeals, raising questions concerning (1) the procedures, burdens, and standards for a §146 action, and (2) the correctness of the district court's decision. The district court's award of priority is affirmed, for the court correctly applied the relevant procedural and substantive law, and error has not been shown in the court's factual findings and conclusions of law.

LITIGATION BACKGROUND

In 2006 Streck filed suit against R&D in the United States District Court for the District of Nebraska, asserting that R&D was infringing Streck's U.S. Patents No. 6,200,500 ("the '500 patent"), the invention of Streck employee Dr. Wayne Ryan; and No. 6,221,668 ("the '668 patent") and No. 6,399,388 ("the '388 patent"), inventions of Dr. Ryan and Streck employee John Scholl. R&D raised the defense that the Streck patents are invalid on the ground that R&D's employee, Dr. Alan Johnson, was the earlier inventor of the same invention as patented by Streck. The

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[1] Streck, Inc. v. Research & Diagnostic Sys., Inc., 744 F. Supp. 2d 970 (D. Neb. 2009).

infringement suit was tried to a jury, and the issue of priority of invention garnered testimonial and documentary evidence by both sides, including the live testimony of seventeen witnesses and nearly 200 exhibits. The jury was instructed:

> R&D must prove by clear and convincing evidence (1) that before the patentee reduced his invention to practice, Dr. Alan Johnson reduced to practice a product or method that included all of the elements of [the asserted claims]; and (2) that Dr. Alan Johnson did not abandon, suppress, or conceal his invention before October 18, 1999.

Streck, Inc. v. Research Diagnostic Sys., Inc., No. 8:06-cv-458, Final Jury Instruction 20, Dkt. No. 319. This instruction was embodied in a special interrogatory for each of the eight patent claims on which the infringement action was focused:

> Has R&D proven by clear and convincing evidence that Dr. Johnson was the first to invent [the specific claim] and did not abandon, suppress or conceal that invention?

Id., Jury Verdict form, Dkt. No. 315. The jury answered "No" with respect to each claim. The jury verdicts were rendered on October 28, 2009, and judgment was entered on October 29, 2009.

Concurrently with the infringement litigation, priority of invention was being contested in an "interference" proceeding in the U.S. Patent and Trademark Office ("PTO"). The interference was "declared" on March 21, 2007 and involved five Ryan and Scholl patents (including the three patents in the infringement suit), having an earliest filing

date of August 20, 1999, and a patent application of Johnson having an earliest filing date of October 18, 1999. The district court denied R&D's motion to stay the infringement suit pending completion of the PTO interference, stating that "Streck has presented evidence of continued alleged infringement that would require injunctive relief that can only be obtained in this court."

On November 2, 2009, the PTO Board of Patent Appeals and Interferences ("the Board") issued its decision, awarding priority to the junior party Johnson. *Johnson v. Ryan*, Interference No. 105,522 (B.P.A.I. Nov. 2, 2009). Streck then filed a §146 action in the Nebraska district court, where the case was assigned to the same district judge who had tried the infringement case. The district court duly awarded priority in favor of the Streck inventors Ryan and Scholl. R&D timely appealed, concurrently with its appeal of the adverse judgment in the infringement suit. The appeals were heard on the same day, and the parties suggested that this court first consider the priority issue presented in the §146 action. The parties agreed that, if this court affirms the district court's decision in the §146 action – including the burden of proof and standard of review employed therein – that conclusion could affect the infringement appeal. This court today decides Appeal No. 2011-1045, the priority issue subject of the §146 action. The decision in *Streck, Inc. v. Research & Diagnostic Systems, Inc.*, Appeal No. 2011-1044, will follow.

THE §146 ACTION

A §146 action requires that there first have been an interference proceeding in the PTO. The losing party may either appeal directly to the Federal Circuit on the PTO record, in accordance with 35 U.S.C. §141; or may obtain a

"remedy by civil action" in district court as provided by 35 U.S.C. §146, followed by appeal to the Federal Circuit.

A. District Court Procedure

Streck filed a civil action under §146, and the parties and the district court agreed that the issue of priority would be decided on the evidentiary record relevant to priority as adduced in the infringement trial, together with the record in the PTO interference proceeding. Section 146 provides for admission of the PTO record in the district court:

> In such suits the record in the Patent and Trademark Office shall be admitted on motion of either party upon the terms and conditions as to costs, expenses, and the further cross-examination of the witnesses as the court imposes, without prejudice to the right of the parties to take further testimony. The testimony and exhibits of the record in the Patent and Trademark Office when admitted shall have the same effect as if originally taken and produced in the suit.

The PTO record was duly admitted. The district court stated that "[t]he record now before the court includes live testimony, evidence that was not presented to the Board, and evidence that conflicts with that provided to the Board. Over fifty exhibits were admitted in the infringement trial that were not considered by the Board in the Interference Action." *Streck*, 744 F. Supp. 2d at 972 (footnote omitted).

The district court stated that its obligation was to find the facts of priority *de novo*, on the entirety of the evidence at trial and in the PTO record. *Id*. at 982. R&D had objected to this procedure, and argues that the district court erred in employing it. R&D states that the district court in

a §146 proceeding must accept the findings of the Board if those findings were supported by substantial evidence in the PTO record. R&D states that it was procedurally incorrect for the district court to make *de novo* findings on issues on which the PTO's findings were supported by substantial evidence in the record before the PTO. Thus R&D argues that the district court should have reviewed each of the Board's factual findings in the interference to determine if the finding was supported by substantial evidence and, if so, the district court should have accepted and applied the Board's finding, refusing to accept new evidence on any such finding or to otherwise reconsider it.

The district court rejected R&D's theory of the role of the district court under §146. The district court cited *Winner International Royalty Corporation v. Wang*, 202 F.3d 1340 (Fed. Cir. 2000), where this court held that "the admission of live testimony on all matters before the Board in a section 146 action, as in this case, makes a factfinder of the district court and requires a *de novo* trial." 202 F.3d at 1347. The Federal Circuit held that the district court must find the facts *de novo*, even if "the live testimony before the district court might be of the same or similar to testimony before the Board in the form of affidavits and deposition transcripts." *Id.* The court stated that "our holding also establishes a clear rule that *live* testimony admitted on all matters that were before the Board triggers a *de novo* trial." *Id.* at 1347-48.

Section 146 provides that the civil action is "without prejudice to the right of the parties to take further testimony." In *Agilent Technologies, Inc. v. Affymetrix, Inc.,* 567 F.3d 1366 (Fed. Cir. 2009) the court explained that "[s]ection 146 affords a litigant the option of shoring up evidentiary gaps." 567 F.3d at 1380; *see also Koninklijke Philips Elecs. N.V. v. Cardiac Sci. Operating Co.*, 590 F.3d

1326, 1332 (Fed. Cir. 2010) ("§146 grants parties the right to present new testimony . . . .").

This court thus recognized that the opportunity to receive additional evidence, as well as to hear and see witnesses at trial, can facilitate findings having depth beyond that available on review of a cold record. *See Winner*, 202 F.3d at 1347 ("[B]ecause the district court may observe witnesses under examination and cross-examination it can have a 'powerful advantage' over the Board which can never receive testimony in such a manner." (quoting *Burlington Indus., Inc. v. Quigg*, 822 F.2d 1581, 1582 (Fed. Cir. 1987)); *cf. Hyatt v. Kappos*, 625 F.3d 1320, 1331 (Fed. Cir. 2010) (en banc), *cert. granted*, 131 S. Ct. 3064 (2011) ("Congress intended that applicants would be free to introduce new evidence in §145 proceedings subject only to the rules applicable to all civil actions, the Federal Rules of Evidence and the Federal Rules of Civil Procedure.").[2]

R&D also argues that, assuming some new evidence may be considered, it is only when the evidence adduced in the district court is in conflict with the evidence before the Board that the district court may make *de novo* findings as to the facts to which that evidence relates. Neither statute nor precedent supports such a distinction, whose impracticality was explored in *Winner*:

> [I]f the test for determining whether *de novo* adjudication is appropriate were based on exactly what the witness said in the district court and whether it was truly 'new or different' than what was disclosed in affidavits and deposition transcripts of the same

[2] In *Hyatt* the court recognized that sections 145 and 146 are "parallel provisions" that are "to be treated similarly." 625 F.3d at 1330 n.2 (citing *Winner*, 202 F.3d at 1345).

> or other witnesses before the Board, then the district court, and this court on appeal, would be required to search nearly line-by-line through the respective records as to each witness and issue to determine which standard applied. Aside from being difficult, such a test would provide scant guidance for a prospective litigant attempting to discern which standard would apply should it file a section 146 action.

202 F.3d at 1348; *cf. Hyatt*, 625 F.3d at 1336 ("Because the court must determine the weight and import of this new evidence, we have held that the district court in a §145 action must make de novo fact findings with respect to factual issues to which the new evidence relates.").

R&D argues that "*Winner* is not controlling," and that this court's acceptance of the *de novo* §146 standard was modified in *Agilent*. However, the court in *Agilent* did not hold that the district court cannot make its own factual findings unless the evidence in the district court conflicts with the PTO record. To the contrary, in *Agilent* the court held that "[t]he district court's decision to deferentially review the Board's written description holding in the face of newly submitted conflicting evidence constituted legal error." 567 F.3d at 1380. The standard for trial and decision of a §146 action in the district court is not the same as the standard for review by the Federal Circuit in a §141 direct appeal from the PTO on the Board record. *See Dickinson v. Zurko*, 527 U.S. 150, 152 (1999) (on direct appeal, the Federal Circuit applies the standard of review established by the Administrative Procedure Act).

The circumstances of this case highlight the importance of interpreting §146 as we have to date and continue to do here. The Board premised its factual findings on the sworn

statements and documents submitted to it. The statements did not allow for live credibility assessments, however, and the documents submitted to the Board were highly redacted. As discussed below, the district court expressly found, upon examination of the unredacted documents and with the benefit of live testimony from the declarants, that many of the representations upon which the Board relied were not accurate or credible. In other words, the nature of the administrative proceeding limited the scope of the Board's inquiry and potentially the accuracy of its fact finding. Section 146 recognizes that, while the Board is fully capable of assessing all matters presented to it, there are inherent limits to its fact finding function that arise from the sterile nature of a proceeding that is limited to documentary and declaration or deposition evidence.

In accordance with statute and precedent, the district court appropriately considered additional evidence and conducted a *de novo* determination of the issue of priority under §146.

B. Burden of Proof

R&D also argues that the district court misplaced the burden of proof, and that the burden of proof should have been placed on Streck in the §146 action because Streck lost in the PTO. R&D points out that the appellant routinely bears the burden of proof on appeal.

Streck responds that the district court correctly preserved the relationship in priority contests, where the party with the later patent application filing date, that is, the junior party, bears the burden of overcoming the filing date of the earlier entrant into the patenting process. Streck states that since the §146 action is a *de novo* proceeding, not

an appeal from an adverse decision, the junior party still has that burden.

Placement of the burdens in interactive litigation is not simple. As the Court noted in *Microsoft Corp. v. i4i Limited Partnership*, 131 S. Ct. 2238 (2011), "[h]istorically, the term [burden of proof] has encompassed two separate burdens: the 'burden of persuasion' (specifying which party loses if the evidence is balanced), as well as the 'burden of production' (specifying which party must come forward with evidence at various stages in the litigation)." 131 S. Ct. at 2245 n.4. Because, as discussed above, a §146 action is a new civil proceeding subject to *de novo* determination, the district court properly placed the burden of persuasion on R&D.

C. Standard of Proof

In the PTO the Board applied the standard of proof of priority by a preponderance of the evidence, because the Johnson and the Ryan applications were initially copending in the PTO. *See Bosies v. Benedict*, 27 F.3d 539, 541-42 (Fed. Cir. 1994) (for copending applications, priority is determined by a preponderance of the evidence). The district court adopted the same standard for the §146 proceeding, and recognized that in the infringement litigation the jury had been instructed that invalidity must be proved by clear and convincing evidence. The district court stated that for the §146 action "[t]he court will independently review those facts presented at trial and in the interference proceeding and will apply the preponderance of evidence standard in analyzing those facts." *Streck*, 744 F. Supp. 2d at 982 n.7. We agree that the standard of proof in this §146 proceeding was by a preponderance of the evidence and was, as the parties note, a lesser burden than was imposed on R&D in the infringement proceeding, where invalidity based

on R&D's asserted prior invention was required to be proved by clear and convincing evidence.

PRIORITY OF INVENTION

The primary legal criteria of patent-focused invention are "conception" and "reduction to practice," with some additional attributes applicable to various factual situations. Determination of priority as between competing inventors is guided by rules that have arisen from the activities of technology-based creativity. In priority disputes, including disputes under §146, the questions of conception and reduction to practice are deemed to be matters of law, founded on facts. The district court's determination of priority in a §146 action is reviewed *de novo* on appeal, and the court's factual findings supporting its legal conclusions are reviewed for clear error. *Rolls-Royce, PLC v. United Techs. Corp.*, 603 F.3d 1325, 1330 (Fed. Cir. 2010); *see DSL Dynamic Scis. Ltd. v. Union Switch & Signal Inc.*, 928 F.2d 1122, 1125 (Fed. Cir. 1991).

On this appeal, R&D directs our attention to the PTO's findings and conclusions that favor R&D. The district court's opinion explains why it made findings and reached a conclusion that differed from that of the PTO, citing the new evidence that was adduced in the district court proceeding, and various conflicts with the evidence presented to the PTO. We discern no error in the district court's findings and conclusions, as we next discuss.

A. The Technology

Hematology instruments, such as are used to analyze samples of blood, measure the different types of blood cells in the sample. Government regulations, and sound practice, require that these instruments be regularly checked for

accuracy. This checking for accuracy is achieved through the use of "controls" of known blood composition, that verify whether an instrument is accurately reading the blood sample. Such controls are made from chemically stabilized blood cells, or analogs thereof that simulate or mimic the relevant characteristics of blood cells. Laboratories, hospitals, clinics, and doctor's offices use such controls to test whether the hematology instrument is working accurately, by running the control through the instrument and comparing the instrument's analysis of the control with the assay sheet provided by the manufacturer of the control. Both Streck and R&D are in the business of providing such controls.

The invention at issue is an "integrated reticulocyte control," which contains at least a reticulocyte component[3] combined with a white blood cell component capable of identifying the five types of white blood cells: lymphocytes, monocytes, neutrophils, eosinophils, and basophils. Although not an issue, the parties point out that such a control typically also contains a mature red blood cell component and a platelet component, and some claims so state. In the district court the priority determination was focused on the following interference count as developed in the PTO proceeding:

> A hematology control composition comprising:
>
> a) a stabilized reticulocyte component; and

[3] The district court defined "reticulocyte" as "immature anucleate red blood cells containing some ribonucleic acid." *Streck, Inc. v. Research Diagnostic Sys., Inc.*, No. 8:06-cv-458, 2008 WL 4891132, at *11 (D. Neb. Nov. 12, 2008).

> b) a fixed and stabilized white blood cell component capable of exhibiting a five-part differential.

The count was claim 1 of Ryan's '668 patent and claim 46 of the Johnson application.

B. Conception

Before 1996, hematology instruments measured reticulocytes and white blood cells separately, in order to avoid error in counting or classifying due to interference between the various blood components. The instruments required separate blood samples for the separate measurements, and separate controls were required to check the accuracy of the instrument. Both Streck and R&D knew that instrument makers were attempting to develop an integrated hematology analyzer that could concurrently measure reticulocytes and the five types of white blood cells in the same blood sample. No control existed for such an instrument. It was understood that eliminating interference among the various components of the blood would be critical for such analysis, and essential for the control to determine whether the instrument was accurately classifying and counting the various blood components.

The controls that then existed were limited each to a specific blood component, as were the instruments they controlled. The district court found that Dr. Ryan in late 1993 conducted experiments and successfully determined that it was feasible to create a control that would measure reticulocytes without interference from the white blood cells that were concurrently measured. In the district court, both Streck's and R&D's expert witnesses testified that Ryan's November-December 1993 work was a conception of the subject matter of the interference count, although R&D's

expert had presented a contrary opinion by declaration in the PTO.

The district court found that Ryan was the first to conceive of the subject matter of the count. R&D does not challenge that ruling on this appeal.

C. Reduction to Practice

The district court found and R&D agrees that Ryan reduced to practice the subject matter of the count beginning in 1997 and continuing into 1998 and 1999. R&D argued that Dr. Johnson, although second to conceive, had reduced the invention to practice before the Ryan filing date and before Dr. Ryan's actual reduction to practice. R&D also argued that Ryan had not shown diligence from his date of conception to his actual or constructive reduction to practice.

To establish an actual reduction to practice, it is necessary to show that the claimant had possession of the subject matter of the count and that it was shown or known to work for its intended purpose. *Mycogen Plant Sci., Inc. v Monsanto Co.*, 243 F.3d 1316, 1332 (Fed. Cir. 2001). When testing is needed to establish that an invention worked for its intended purpose, the inventor must have recognized that the tests were successful. *Estee Lauder Inc. v. L'Oreal, S.A.*, 129 F.3d 588, 594-95 (Fed. Cir. 1997). The parties do not dispute that experimental testing was needed here to establish actual reduction to practice.

Witnesses explained that for the control to work for its intended purpose, the control must test whether the instrument is accurately measuring the separate components of the blood. The expert witnesses agreed that the control must correctly test the accuracy of the hemotology instru-

ment, and that the control must be sufficiently stable over an extended period of time. The district court found that the intended purpose was to provide an integrated control that would be free of inaccuracy due to interference from reticulocytes, and thus that determination of whether such interference between blood components occurred was required for reduction to practice.

R&D's position is that Dr. Johnson reduced the invention to practice in July 1996. R&D asserts that Johnson prepared sample controls that combined existing white blood cell and recticulocyte controls in 1996, and that two such experiments were reductions to practice of the interference count. Dr. Johnson testified that the samples called Control 1 and Control 2 contained a reticulocyte component and a white blood cell component, and that an assistant ran these samples, along with some unrelated samples, on a prototype of the Abbott Cell-Dyn 4000 instrument, a proposed new Abbott instrument that was intended to have the capability of integrated analysis.

On reviewing the evidence, the district court found that Dr. Johnson's 1996 experiments were directed to determining the stability of the combination of components, not the correctness of the count. R&D does not dispute this finding, but argues that testing of stability sufficed to meet the interference count. R&D states that the district court applied the wrong legal standard for determining when a composition works for its intended purpose, and that it suffices that Johnson used his 1996 controls on a prototype of an integrated hematology analyzer.

The district court found, referring to the expert testimony, that "the difficulty in developing an integrated control was the tendency for the hematology instrument to recognize the reticulocyte analogs incorrectly and count

them as white blood cells, resulting in an inaccurate result." *Streck*, 744 F. Supp. 2d at 985. The court found that the purpose of the invention was to provide an integrated control that would be free of inaccuracy due to interference among various blood components, and that therefore whether the control accurately measured the components without interference was required in order to know whether the control would work for its intended purpose. "Proof of actual reduction to practice requires more than theoretical capability . . . ." *Newkirk v. Lulejian*, 825 F.2d 1581, 1583 (Fed. Cir. 1987). The district court was correct in holding that for actual reduction to practice the control must have been shown to be effective for its control purpose: that is, determining the accuracy of the instrument.

The court also found R&D's evidence deficient, stating that it "consists mainly of the uncorroborated testimony of the inventor, Dr. Johnson, that he created a composition and it worked," and that there was "no evidence of precisely what went into the compositions that Dr. Johnson later deemed successful." *Streck*, 744 F. Supp. 2d at 985 ("The court was not provided with evidence of the components of either the commercial or prototype compositions that were mixed with recticulocytes in the Johnson Controls 1-4 experiments."). The court found that the evidence "relates more to the issue of the stability of the composition over time and not to the issue of accuracy of an instrument's measurements in light of potential interference between the various components in the control composition." *Id.* at 984-85.

Referring to the evidence of later work done at R&D, where controls were developed for integrated analysis and were routinely tested for interference among blood components, the court stated that "[t]here is no evidence that Dr. Johnson evaluated this sort of evidence in connection with

the experiments he ran in 1996." *Id.* at 985. The district court deemed it "[e]qually significant, if he did not use scattergrams throughout his [1996] experiment, he did not retain sufficient documentation to corroborate his alleged invention." *Id.* The court explained that "[s]cattergrams are visual representations of the positioning of cell populations by type, according to an instrument's mathematical algorithms (or software). The positioning is generally determined by cell size, shape, and the amount of light it scatters." *Id.* at 977. In the infringement trial, the experts for both sides agreed that such analysis is necessary in designing and developing integrated controls. Although R&D argues on this appeal that the district court placed too much weight on scattergram analysis, the record contains no evidence of determination by R&D, by any method, of whether the 1996 samples were effective in avoiding interference among blood components.

R&D also argues that analysis of efficacy, by scattergram or any method, is not required for reduction to practice, for the interference count does not include analysis of efficacy. The district court found that the count relates to "controls," which requires effectiveness as a control. *Id.* at 976 ("A control composition that 'worked' would be one that lacked interference, with cells properly positioned, that was stable over time."). The intended purpose need not be explicitly included in the count of the interference, *DSL Dynamic*, 928 F.2d at 1125 (citing *Elmore v. Schmitt*, 278 F.2d 510 (CCPA 1960)), but establishing an actual reduction to practice requires demonstration that the invention worked for its intended purpose. The district court observed that the compositions that were said to have been tested in 1996 were mentioned in a later document of Dr. Johnson as producing negative results, and were avoided when he later designed an integrated control.

The sufficiency of testing to show an invention works for its intended purpose is a factual issue. *z4 Techs., Inc. v. Microsoft Corp.*, 507 F.3d 1340, 1352 (Fed. Cir. 2007); *see also Scott v. Finney*, 34 F.3d 1058, 1063 (Fed. Cir. 1994) (courts must "examine[] the record to discern whether the testing in fact demonstrated a solution to the problem intended to be solved by the invention"). The district court made findings, including findings of credibility and weight, and applied the law to the found facts. The district court's findings of fact have not been shown to be clearly erroneous, and the court stated and applied the correct law of reduction to practice. The court correctly held that R&D did not establish an actual reduction to practice in its 1996 experiments. R&D proffered no other evidence purporting to show reduction to practice before Streck's actual reduction to practice.

The district court also discussed Streck's evidence of actual reduction to practice. R&D's expert Dr. Simson testified in the district court that Streck's experiments were a successful reduction to practice, stating "Dr. Ryan had demonstrated previously, as we heard in this trial, controls that would work for their intended purpose sometime in late 1997." *Streck*, 744 F. Supp. 2d at 981 (quoting T. Tr. (Vol. VII) at 1386). As R&D does not challenge Streck's actual reduction to practice on this appeal, we do not review the district court's analysis of Streck's evidence. And in view of our affirmance of the district court's ruling that R&D had not established an actual reduction to practice before Streck's actual reduction to practice, we need not reach the rulings on diligence and abandonment, *id.* at 986 n.11, which the district court made for the sake of completeness.

CONCLUSION

On this appeal, R&D's principal argument is not that the district court erred on the entirety of the evidence, but that the Board's findings should prevail if they were supported by substantial evidence before the Board, and therefore that the district court's *de novo* procedure was incorrect. However, as we have observed, §146 establishes *de novo* review. The purpose of §146 is to bring to bear, upon the contested issues of priority of invention, the procedures and rules of federal litigation. The statutory alternative of a civil action in the district court following the decision of the PTO tribunal implements the purpose whereby judicial process is the final arbiter of the rights and issues administratively assigned to the PTO. On the entirety of the evidence, the district court's findings and conclusion that R&D did not establish a reduction to practice with Johnson's 1996 experiments is affirmed. The court correctly awarded priority of invention to Ryan and Streck.

AFFIRMED